



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250555

| | |
|--------------------|---------------------------------------------------|
| Product: | INDOMETHACIN |
| Lot: | 250555 |
| Expiry date: | 12/05/2028 |
| Reference: | Cumple PhEur11.6 |
| Synonyms: | |
| Formule: | C ₁₉ H ₁₆ ClNO ₄ |
| Poids moléculaire: | 357,79 g/mol |

| Assay | Result | Specification | |
|---------------------------|---------------|------------------|---|
| Identification | Conform (A,B) | Test PhEur (A,B) | |
| Organoleptic properties | Conform | PhEur | |
| Elemental impurities | Conform | Test PhEur | # |
| Related substances (UPLC) | Conform | Test PhEur | |
| Loss on drying | 0,06 % | <= 0,5 % | |
| Sulphated ashes | 0,01 % | <= 0,1% | |
| ASSAY (UPLC) | 99,9 % | 98,0 - 102,0 % | |
| Unspecified Impurities | < 0,05 % | <= 0,10 % | |
| Total impurities | < 0,05 % | <= 0,3 % | |
| Residual solvents | Conform | Test PhEur | # |
| Nitrosamine impurities | Conform | Test PhEur | # |

Organoleptic characteristics: Crystalline powder, white or yellow. Practically insoluble in water, fairly soluble in 96% ethanol, practically insoluble in heptane.

Conservation: In tightly closed containers. Protect from light.

Date of analysis: 07/03/2025

Judgement:
APPROVED

Responsible: B. Chia

Technical director: Montserrat Enrique

Manufacturer: F00356 CSPC OUYI PHARMACEUTICAL CO. LTD.

Manufacturer batch: 174240505

| Produit | Nom | Capacité | Lot |
|---------|--------------|----------|------------|
| 1153302 | INDOMETACINA | 50 g | 250555-I-1 |
| 1153302 | INDOMETACINA | 50 g | 250555-I-2 |
| 1153302 | INDOMETACINA | 50 g | 250555-I-3 |
| 1153302 | INDOMETACINA | 50 g | 250555-I-4 |
| 1153304 | INDOMETACINA | 250 g | 250555-N-1 |
| 1153304 | INDOMETACINA | 250 g | 250555-N-2 |

| | | | |
|---------|--------------------|-------|------------|
| 1153304 | INDOMETACINA | 250 g | 250555-N-4 |
| 1200261 | INDOMETACINA | 10 g | 250555-F-2 |
| 1200261 | INDOMETACINA | 10 g | 250555-F-4 |
| 1200261 | INDOMETACINA | 10 g | 250555-F-5 |
| 1200261 | INDOMETACINA | 10 g | 250555-F-7 |
| 1200261 | INDOMETACINA | 10 g | 250555-F-8 |
| 1370198 | INDOMETACINA (FLB) | 250 g | 250555-N-3 |
| 1370203 | INDOMETACINA (FLB) | 10 g | 250555-F-1 |
| 1370203 | INDOMETACINA (FLB) | 10 g | 250555-F-3 |
| 1370203 | INDOMETACINA (FLB) | 10 g | 250555-F-6 |

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

ACOFARMA DISTRIBUCIÓN, S.A.
C/ Llobregat, 20 - 08223 Terrassa (Barcelona)
Tel./ 93-736.00.88
www.acofarma.com

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